

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

DAVID PHILIP SHOCKLEY,

Plaintiff,

V.

BLUE BELL CREAMERIES, INC.,
a Delaware corporation,
BLUE BELL CREAMERIES U.S.A., INC.,
a Delaware Corporation,
BLUE BELL CREAMERIES, L.P.,
a Delaware Limited Partnership,

Defendants.

CIVIL ACTION NO. 1:15-cv-425

JURY DEMAND

COMPLAINT

Plaintiff DAVID PHILIP SHOCKLEY (“Plaintiff”), by and through his counsel Pritzker Olsen, P.A., and Lynn, Tillotson, Pinker & Cox, L.L.P., upon information and belief, states and alleges as follows:

NATURE OF THE CASE

1. This action arises out of the longstanding and widespread contamination of “Blue Bell” brand ice cream products with *Listeria monocytogenes*, a deadly foodborne pathogen.

2. Defendants BLUE BELL CREAMERIES, INC., BLUE BELL CREAMERIES U.S.A., INC., and BLUE BELL CREAMERIES, L.P. (hereafter collectively referred to as “Defendants” or “Blue Bell”) individually and jointly designed, manufactured, distributed, marketed and sold contaminated Blue Bell brand ice cream products.

3. As early as 2010, Blue Bell produced its ice cream at facilities infested with *Listeria monocytogenes* and as a result, produced ice cream products contaminated with the deadly pathogen. Blue Bell's ice cream products caused numerous listeriosis infections beginning in 2010 and lasting until a sweeping recall of all its ice cream products in 2015.

4. Plaintiff DAVID PHILIP SHOCKLEY (hereafter "Plaintiff") consumed a variety of Blue Bell ice cream products contaminated with *Listeria monocytogenes* and subsequently developed a severe listeriosis infection. The bacteria infected Plaintiff's blood and migrated to his brain where it caused extensive damage, leaving him unconscious and near death.

5. Plaintiff survived but even after well over a year of intensive neurological treatment, therapy and rehabilitation, he continues to suffer from, among other injuries, posterior fossa syndrome ("PFS"), a severe neurological syndrome caused by damage to the brainstem and cerebellum and characterized by cognitive, emotional, behavioral, motor, language and speech-related dysfunction.

6. *Listeria monocytogenes* is a well-known food safety risk in the production of ice cream and other ready-to-eat foods because the bacteria tends to thrive in food processing environments.

7. For this reason, and because *Listeria monocytogenes* is one of the most deadly foodborne pathogens, safe production of ready-to-eat foods, including ice cream, requires food safety systems specifically designed to prevent *Listeria* contamination of products and the food processing environment.

8. Blue Bell utterly failed to design and implement sanitation and safety programs that would have prevented the sort of infestation and contamination that occurred at its facilities over a period of years. Among other acts and omissions, Blue Bell failed to implement adequate

environmental and product testing, failed to effectively sanitize and maintain its production environment and equipment, failed to adequately train and supervise its employees, failed to maintain a production process which eliminated the risk of cross contamination and otherwise failed to adopt and implement food safety policies and procedures that would prevent the sort of systemic and lasting *Listeria monocytogenes* infestation that occurred in its food production facilities.

9. As a result of its manufacture, distribution, marketing and sale of defective ice cream products and its negligent acts and omissions, Defendants caused Plaintiff's listeriosis infection. As a result, Plaintiff has suffered profound brain damage; other physical injuries; physical pain; disability, including ataxic dysarthria, dizziness, inability to balance and coordinate movements, fine motor skill impairment, dysphagia, slowed cognitive processing, and slowed movements; mental anguish, including a clear diminished enjoyment of life; extensive, invasive and long-term medical treatment; and a loss of earnings and of future earning capacity. Plaintiff's injuries and losses are permanent in nature and will continue for the rest of his life.

PARTIES

10. Plaintiff DAVID PHILIP SHOCKLEY is a citizen and resident of the State of Maryland.

11. Upon information and belief, Defendant BLUE BELL CREAMERIES, INC., is a corporation organized under the laws of Delaware with its corporate headquarters in Texas.

12. Upon information and belief, BLUE BELL CREAMERIES U.S.A., INC., is a corporation organized under the laws of Delaware with its corporate headquarters in Texas.

13. Upon information and belief, BLUE BELL CREAMERIES, L.P., is a limited partnership organized under the laws of Delaware with its corporate headquarters in Texas. Upon information and belief, none of the partners are residents of Maryland.

14. Defendants BLUE BELL CREAMERIES U.S.A., INC., BLUE BELL CREAMERIES U.S.A., INC., and BLUE BELL CREAMERIES, L.P., collectively operate and control the manufacture, distribution, marketing and sale of Blue Bell brand ice cream products.

15. Upon information and belief, each Defendant acts as the agent, servant, partner and/or joint venture of each of the other Defendants in the coordinated manufacture, distribution, marketing and sale of Blue Bell brand ice cream products. At all relevant times, each Defendant was acting within the scope of its agency, service, employment, partnership and/or joint venture and rendered substantial assistance and encouragement to the other Defendants in the production, distribution, marketing and sale of Blue Bell brand ice cream products. Each Defendant is therefore responsible for the acts and omissions of its co-Defendants and each Defendant is both individually and jointly and severally liable to Plaintiff for his injuries.

16. Upon information and belief, Blue Bell produces its ice cream products at processing facilities in Brenham, Texas, Broken Arrow, Oklahoma and Sylacauga, Alabama.

17. According to the Blue Bell website, its products are available in about thirty percent (30%) of the nation's supermarkets. Blue Bell claims to rank as one of the top three best-selling ice creams in the country. Its products are sold in twenty three (23) states including: Alabama, Arizona, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, Texas, South Carolina and parts of Arkansas, Colorado, Illinois, Indiana, Kansas, Kentucky, Missouri, New Mexico, Nevada, Ohio, Tennessee, Virginia and Wyoming.

JURISDICTION AND VENUE

18. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and Defendants.

19. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District; the Defendants' respective corporate headquarters are in this District; and the Defendants conduct substantial business in this District.

FACTUAL BACKGROUND

Listeriosis and the Blue Bell Outbreak

20. Listeriosis is a serious illness resulting from consumption of food contaminated with a gram-positive rod-shaped bacterium known by the genus *Listeria* and species *monocytogenes*.

21. *Listeria monocytogenes* is one of the most virulent and deadly foodborne pathogens with a fatality rate of over twenty percent (20%). Virtually all people who contract listeriosis require hospitalization. Those who are elderly, immuno-compromised or pregnant are particularly vulnerable.

22. Cooking food to an appropriate temperature or pasteurization will kill *Listeria monocytogenes* and prevent human infection; however, contact with *Listeria monocytogenes* after such a "killstep" will re-contaminate the food product.

23. This risk is heightened because *Listeria monocytogenes* tends to thrive in food processing environments, particularly in floor drains and other cool, damp areas. Moreover, *Listeria monocytogenes* can easily be transferred from one area of a processing facility to another

through, for example, simple touching of equipment, water, mist, workers' clothing, shoes and hands. In contrast to most other harmful bacteria, *Listeria monocytogenes* will grow slowly on foods stored in a refrigerator, and freezing has very little detrimental effect on the organism.

24. These characteristics render processed ready-to-eat food products, like ice cream, particularly susceptible to contamination with *Listeria monocytogenes*.

25. Since 1985, the United States Food and Drug Administration ("FDA") has maintained a "zero tolerance" policy for *Listeria monocytogenes* in ready-to-eat foods. FDA considers ready-to-eat foods to be adulterated under § 402(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) if any *Listeria monocytogenes* is detected in either of two 25-gram samples.

26. In 2003, the United States Food and Drug Administration ("FDA") and the Food Safety and Inspection Service ("FSIS") of the United States Department of Agriculture ("USDA"), in consultation with the Centers for Disease Control and Prevention ("CDC"), released a qualitative assessment of relative risk associated with certain ready-to-eat foods. Milk, butter, cream and other high fat dairy products were among the products found to pose the highest risk of being associated with listeriosis.

27. Thus, responsible producers of ready-to-eat foods, including ice cream, have been fully aware of the public health risks posed by *Listeria monocytogenes* for decades.

28. Because *Listeria monocytogenes* contamination is such a well-known risk in the production of ready-to-eat foods, especially certain dairy products, and is so dangerous when consumed, ready-to-eat food manufacturers have long implemented food safety measures focused on preventing *Listeria monocytogenes* contamination of food processing environments and products.

29. Responsible producers of ready-to-eat foods adopt and enforce written, up-to-date food safety policies and procedures designed to both prevent *Listeria monocytogenes* from entering the processing environment and detect its presence in environment and product.

30. The hallmarks of safe ready-to-eat food production include, but are not limited to, the following:

- a. The adoption of current good manufacturing practices;
- b. The implementation and enforcement of modern sanitation standard operating procedures;
- c. Current, written, validated and enforced Hazard Analysis and Critical Control Point (“HACCP”) assessments and procedures;
- d. Training for employees on effective cleaning and sanitation;
- e. Highly aggressive cleaning techniques;
- f. Regular and systematic action focused on sanitation and cleanliness;
- g. Preventative maintenance of equipment;
- h. Modern equipment and production processes designed to prevent bacterial contamination and cross-contamination;
- i. Testing programs designed to ensure the efficacy of sanitation and food safety policies and procedures, including, but not limited to: daily sampling and testing, swabbing sufficient surfaces within the environment, and holding product from the market pending testing results; and
- j. Consultation with appropriate experts, including, but not limited to, microbiologists and sanitarians.

31. In an effort to stop listeriosis outbreaks as early as possible, the CDC, in collaboration with state public health officials, actively monitor listeriosis cases throughout the country.

32. When possible, state and CDC labs perform a genetic subtyping process known as Pulsed-Field Gel Electrophoresis (“PFGE”) on samples from sickened individuals. The results—akin to genetic fingerprints—are then loaded to a national database known as “PulseNet” where they are can be compared to each other and stored for future reference.

33. This system alerts the CDC when the number of listeriosis cases spikes or when a group of listeriosis cases are caused by the same, or closely related, genetic strain of the bacteria. The CDC then investigates those cases as a single-source outbreak.

34. The CDC can also perform an even more precise genetic test on *Listeria* isolates known as whole genome sequencing or “WGS.” The WGS “fingerprint” provides further insight into the relatedness of *Listeria* samples.

35. In March of 2015, the CDC, in conjunction with state and local health departments, detected a cluster of five listeriosis infections in Kansas. All five (5) people were patients at the same hospital and contracted their illness between January 2014 and January 2015.

36. Three (3) of the five (5) listeriosis patients died as a result of their infections.

37. WGS testing on samples obtained from the sickened individuals revealed that four (4) of the five (5) samples were highly related.

38. Further investigation of the cluster implicated a single-serving Blue Bell product called “Scoops” as the common food source among sickened patients.

39. Invoices provided by the Kansas hospital to the Kansas Department of Health and Environment indicate that the Blue Bell Scoops product came from Blue Bell facilities in Texas and in Oklahoma.

40. In an unrelated investigation, the South Carolina Department of Health and Environmental Control had isolated *Listeria monocytogenes* from the following Blue Bell ice cream products collected from a distribution center: Chocolate Chip Country Cookie Sandwiches and Great Divide Bars.

41. In response to the findings in South Carolina, the Texas Department of State Health Services collected product samples from the Blue Bell production facility in Brenham, Texas. These samples yielded *Listeria monocytogenes* from the same two products as tested by South Carolina investigators and also from the Scoops product, which was made on the same production line.

42. Three (3) *Listeria monocytogenes* strains isolated from ice cream samples had PFGE patterns genetically indistinguishable from those that sickened four (4) of the Kansas patients.

43. *Listeria monocytogenes* samples with four (4) additional PFGE patterns were also isolated from Blue Bell product samples.

44. The CDC ultimately concluded that all five (5) listeriosis patients from the Kansas hospital contracted their infections as a result of consuming contaminated Blue Bell ice cream.

45. On March 13, 2015, in response to the investigation and mounting evidence of a persistent *Listeria monocytogenes* infestation, Blue Bell initiated a recall limited to products from the implicated production line, including the Scoops product.

46. On March 22, 2015, the Kansas Department of Agriculture isolated *Listeria monocytogenes* from a previously unopened single-serve Blue Bell product obtained from the Kansas hospital associated with the outbreak. This cup was produced at Blue Bell's Broken Arrow, Oklahoma facility in April of 2014.

47. Additional samples of Blue Bell-brand 3 oz. institutional/food service chocolate ice cream cups collected from the company's Oklahoma facility have also yielded *Listeria monocytogenes* strains. The isolates from ice cream cup samples were indistinguishable from each other by pulsed-field gel electrophoresis (PFGE), but were different from those isolated from patients in Kansas and from the other Blue Bell ice cream products previously sampled in Texas and South Carolina. According to the CDC, the pattern is rare.

48. On March 23, 2015, Blue Bell expanded the initial recall to include single-serving 3 oz. institutional/food service cups of vanilla, strawberry and chocolate ice cream.

49. The recalled Blue Bell 3 oz institutional/food service ice cream cups were distributed in Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia and Wyoming via food service accounts. The cups were sold to institutions, such as schools, nursing homes and hospitals.

50. As part of the ongoing investigation, FDA inspected Blue Bell's facilities. FDA obtained product samples and ultimately isolated *Listeria monocytogenes* from a 1-pint container of Blue Bell banana pudding ice cream produced at the Oklahoma facility.

51. FDA environmental testing also showed the presence of *Listeria* at Blue Bell's production facilities in both Oklahoma and Alabama.

52. On April 3, 2015, Blue Bell suspended operations at its Oklahoma facility.

53. On April 7, 2015, Blue Bell issued its third recall. This time it recalled all products produced on the same line as the banana pudding ice cream that tested positive but limited its recall to products produced between February 12, 2015, and March 27, 2015.

54. As public pressure on the company mounted, Blue Bell began its own testing. It reported that samples from half gallon chocolate chip cookie dough ice cream produced between March 17, 2015, and March 27, 2015 tested positive for *Listeria monocytogenes*.

55. On April 20, 2015, Blue Bell finally recalled all of its products from all facilities, including ice cream, frozen yogurt, sherbet and frozen snacks.

56. Meanwhile, because the large number of product positives and genetic strains involved indicated a pervasive and longstanding problem, the CDC undertook a retrospective analysis of *Listeria* samples on the PulseNet database to determine if any prior listeriosis cases could be linked to the various genetic strains associated with Blue Bell products.

57. This analysis revealed that three (3) Texas patients from 2011 through 2014 were genetically linked to strains found in ice cream produced at Blue Bell's Oklahoma facility based on both PFGE and WGS analysis. All three (3) were hospitalized for unrelated reasons when they contracted listeriosis.

58. A short time later, the CDC identified two (2) additional patients, one (1) from Oklahoma and one from Arizona, who were also PFGE and WGS matches to samples from Blue Bell ice cream produced at its Oklahoma facility.

59. The CDC published the following infographic summarizing its findings as of April 21, 2015:



60. The CDC and state and local public health agencies are continuing to search for other listeriosis cases linked to Blue Bell through PulseNet.

FDA Inspections and a History of *Listeria* Contamination

61. The multiple listeriosis cases linked to Blue Bell products triggered a formal FDA inspection of Blue Bell's Broken Arrow, Oklahoma, Brenham, Texas and Sylacauga, Alabama production facilities in March and April of 2015.

62. The results revealed a longstanding and pervasive *Listeria monocytogenes* infestation and a manifestly ineffective sanitation program.

63. FDA inspectors examined each production facility and reviewed safety records.

64. At the conclusion of the inspections, the inspectors issued their findings in a document called a “Form 483.” The Form 483 records the inspectors’ observations of any conditions that in their judgment, constitute violations of the Food Drug and Cosmetic Act and related federal law.

65. More specifically, the inspectors’ Form 483 “observations” reflect clear, specific and significant instances where a food has been adulterated or is being prepared, packed or held under conditions whereby it may become adulterated or rendered injurious to health.

66. In all, FDA inspectors recorded twenty six (26) conditions constituting violations of federal law and posing significant risks to the safety of Blue Bell products.

67. Attached as Exhibits 1-3 are copies of the Form 483s for the three (3) Blue Bell facilities published by the FDA with redactions.

68. At the Brenham, Texas production facility, FDA inspectors noted that even after *Listeria* positives in both product and processing environment and after “routine cleaning and sanitizing,” *Listeria* remained present in the environment, including food-contact surfaces.

69. The FDA’s Form 483 Observation 1 from the Brenham facility states that Blue Bell failed “to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.”

70. The FDA’s Form 483 Observation 2 from the Brenham facility states that Blue Bell’s “procedure used for cleaning and sanitizing of equipment has not been shown to provide adequate cleaning and sanitizing treatment.”

71. Observations 1 and 2 from the Brenham facility were supported by the following testing results and sanitation failures:

- a. *Listeria monocytogenes* positive from “Great Divide Bar” manufactured on January 12, 2015, and distributed between January 13, 2015, and February 10, 2015;
- b. *Listeria monocytogenes* positive from “Chocolate Chip Country Cookie” manufactured on January 20, 2015, and distributed between January 20, 2015, and February 11, 2015;
- c. After ceasing operations on January 30, 2015, for routine cleaning and overhauling of a production line, there were two (2) additional *Listeria monocytogenes* positive environmental samples: one on February 19, 2015, and another on February 21, 2015; and
- d. Blue Bell resumed operation of the line linked to the positive tests and performed routine cleaning and sanitizing of the line, yet there were nonetheless two (2) *Listeria monocytogenes* positives from two (2) different food contact surfaces on March 9, 2015.

72. In addition to Observations 1 and 2 relating to extensive *Listeria monocytogenes* contamination and ineffective cleaning at the Brenham facility, FDA inspectors noted the following violations, among others: failure to prevent condensation from contaminating food and food contact surfaces; failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food; and failure to maintain buildings in repair sufficient to prevent food from becoming adulterated.

73. The Form 483 from the inspection of Blue Bell's Broken Arrow, Oklahoma facility similarly reflects a *Listeria monocytogenes* infestation and profoundly deficient sanitation program.

74. Most significantly, FDA found that the Blue Bell environmental testing program failed to include the following:

- a. Sampling of food contact surfaces;
- b. Determination of preventative action needed in response to the possible contamination;
- c. Determination of the impact on the products produced on the affected date;
- d. Determination of the *Listeria* species associated with the presumptive positive results; and
- e. Root Cause Analysis of why the cleaning and sanitizing treatments were inadequate in controlling the occurrences of microbiological contamination.

75. As a result of Blue Bell's obviously deficient sampling and sanitation program, among other factors, the Broken Arrow facility had a shocking history of *Listeria* positive test results and a failure of its cleaning and sanitation practices.

76. Observation 3 of the Form 483 issued to the Broken Arrow facility states:

The procedure used for cleaning and sanitizing of equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment.

Specifically, you failed to demonstrate your cleaning and sanitizing is effective in controlling recurring microbiological contaminations. You continued to have presumptive positive environmental test results for *Listeria spp.* And elevated total coliform results following daily cleaning and sanitizing treatments of your equipment and facilities. You reported the results of the sampling program were used as an indicator in determining whether the cleaning and sanitation program was effective. In

response to presumptive positive environmental test results for *Listeria spp.* and the elevated coliform counts, you reported the usual cleaning and sanitation cycle after notification of the results; which may be [redacted] days for *Listeria spp.* and [redacted] for in house total coliform.

(emphasis added)

77. The FDA itemized an array of Blue Bell's internal testing results showing extensive *Listeria* contamination from early 2013 to early 2015, including the following:

- a. Positive *Listeria spp.* samples obtained on 3/19/2013, 4/19/2013, 8/13/2013, 10/18/2013, and 11/12/2013;
- b. Positive *Listeria spp.* samples obtained on 1/13/2014, 1/20/2014 (two separate positive samples), 4/15/2014, 4/22/2014 (three separate positive samples), 8/11/2014 (two separate positive samples), and 11/12/2014; and
- c. Positive *Listeria spp.* samples obtained on 1/13/2015.

78. In addition to the internal testing outlined above, environmental samples collected by the FDA from the Broken Arrow processing facility on 3/24/2015 and 3/25/2015 tested positive for *Listeria monocytogenes*.

79. Most significantly, Blue Bell's internal testing revealed two instances where consecutive repeat samples were positive despite documents asserting that the contaminated areas had been cleaned and sanitized

80. An environmental sample obtained on 1/13/2014 tested "presumptive positive" for *Listeria spp.* Soon after, the area where the sample was obtained was "cleaned and sanitized" according to Blue Bell's procedures. A repeat sample from the same area on 1/20/2014 again tested presumptive positive for *Listeria spp.*

81. Similarly, an environmental sample obtained on 4/15/2014 tested “presumptive positive” for *Listeria spp.* Soon after, the area where the sample was collected was “cleaned and sanitized” according to Blue Bell’s procedures. A repeat sample from the same area on 4/22/2014 again tested presumptive positive for *Listeria spp.*

82. Observation 3 also noted that Blue Bell’s own “coliform” testing of finished product, in-process product and raw ingredients regularly violated regulatory requirements.

83. Coliform testing shows the presence of gram-negative, anerobic rod-shaped bacteria and is used as an indicator for the presence of and growth-potential for microorganisms within a food product.

84. The Oklahoma Department of Agriculture, Food and Forestry issued a regulation limiting the presence of “total coliform” to an amount no greater than twenty (20) Colony Forming Units (CFUs)/mL in finished products of frozen dairy desserts.

85. The FDA inspection revealed that Blue Bell repeatedly and brazenly violated this regulation and apparently released products despite testing showing dangerously high levels of bacteria.

86. The following table summarizes the coliform results over 20 CFUs/mL:

DATE	SAMPLE	RESULT
4/15/14	Finished Product; Pineapple Sherbet	33 CFUs/mL
4/22/14	Finished Product; Homemade Vanilla Ice Cream	34 CFUs/mL
4/25/14	In-Process Product; BBIC Vanilla in Flavor Tank (used for 3oz cups)	105 CFUs/mL
1/12/15	Finished Product; Homemade Vanilla Ice Cream	48 CFUs/mL
1/21/15	Finished Product; Dutch Chocolate Ice Cream	124 CFUs/mL
2/9/15	Finished Product; Dutch Chocolate Ice Cream	275 CFUs/mL
2/24/15	In-Process Product; Homemade Vanilla in Flavor Tank	228 CFUs/mL
2/24/15	Finished Product; Homemade Vanilla Ice Cream	151 CFUs/mL
2/24/15	In-Process Product; Homemade Vanilla in Flavor Tank	[redacted] CFUs/mL
2/24/15	Finished Product; Homemade Vanilla Ice Cream	174 CFUs/mL

DATE	SAMPLE	RESULT
2/26/15	In-Process Product; Homemade Vanilla in Flavor Tank	796 CFUs/mL
2/26/15 – morning	Finished Product; Homemade Vanilla Ice Cream	840 CFUs/mL
2/26/15 – afternoon	Finished Product; Homemade Vanilla Ice Cream	223 CFUs/mL
2/27/15	Finished Product; Homemade Vanilla Ice Cream (resample)	25 CFUs/mL 46 CFUs/mL Too many to count CFUs/mL
2/26/15	In-Process Product; Homemade Vanilla in Flavor Tank	392 CFUs/mL
2/26/15 - morning	Finished Product; Homemade Vanilla Ice Cream	377 CFUs/mL
2/26/15 - afternoon	Finished Product; Homemade Vanilla Ice Cream	[redacted] CFUs/mL
2/27/15	Finished Product; Homemade Vanilla Ice Cream (resample)	88 CFUs/mL 142 CFUs/mL
3/6/15	Finished Product; Sundae Ice Cream	67 CFUs/mL
3/9/15	Finished Product; Homemade Vanilla Ice Cream	121 CFUs/mL
3/16/15	In-Process Product; Homemade Vanilla in Flavor Tank	107 CFUs/mL
3/16/15	Finished Product; Homemade Vanilla Ice Cream	24 CFUs/mL

87. According to the FDA, the only action taken by Blue Bell in response to the positive environmental *Listeria* test results and elevated total coliform results, was the same manifestly ineffective daily cleaning and sanitizing treatments as before the results.

88. More significantly, Blue Bell failed to implement any sort of “test and hold” procedure. “Test and hold” procedures provide that finished food products are not shipped to market until testing results bearing on those products’ safety are complete.

89. Instead of holding any product until after representative microbiological samples were tested and the results reviewed, Blue Bell shipped finished products that later testing results (both environmental and coliform product samples) showed were adulterated.

90. Thus, despite internal *Listeria* and coliform testing indicating that its products were contaminated and sanitation procedures ineffective, Blue Bell continued to ship and sell to consumers obviously dangerous ice cream products.

91. In addition to Observations directly relating to extensive *Listeria* and other potential microbiological contamination and ineffective cleaning at the Broken Arrow facility, FDA inspectors noted the following violations: failure to provide running water at a suitable temperature for cleaning of equipment, utensils and food-packaging materials; failure to prevent drip and condensate from contaminating food, food-contact surfaces, and food-packaging materials; employees did not wash and sanitize hands after each absence from the work station and at any time their hands may have become soiled or contaminated; failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination; failure to use reasonable precautions to ensure that production procedures do not contribute contamination from any source; failure to hold foods which can support the rapid growth of undesirable microorganisms at a temperature that prevents food from becoming adulterated; failure to have smoothly bonded or well-maintained seams on food contact surfaces to minimize accumulation of food particles and organic matter and the opportunity for growth of microorganisms; and the failure to take apart equipment as necessary to ensure thorough cleaning.

92. In response to the illnesses, contamination, recall, and FDA findings, Blue Bell has undertaken “an intensive cleaning program while it simultaneously conducts a new training program for its employees at all four production facilities ...”

93. Blue Bell announced its “fresh start” as follows:

After a thorough review of operations and discussions with an expert microbiologist, it was decided this cleaning and training

program will greatly benefit Blue Bell as it moves forward. Ice cream being produced this week will be used for testing and gathering baseline data and will not be sold to the public.

Training and future improvements at Blue Bell include:

- Highly aggressive cleaning techniques
- Increased actions focused on sanitation and cleanliness
- Strengthening of standard operating procedures
- Enhancements to its preventative maintenance program
- Equipment design changes

94. Among other changes Blue Bell implemented as a result of the outbreak and recall were the following:

- a. The implementation of a “test and hold” program where the company would test products and await results before sending its products to market;
- b. The development of an improved daily cleaning and sanitizing system;
- c. An 800 percent increase in the swabbing and testing of the production plant environment;
- d. A system of daily testing by an outside microbiology lab; and

95. The changes implemented by Blue Bell following the outbreak were widely adopted in the ready-to-eat food production industry prior to the outbreak.

96. Responsible ready-to-eat food manufactures do not distribute and sell products that their own internal testing indicates are not safe for consumption.

97. Responsible ready-to-eat food manufacturers do not wait for illnesses, deaths and recalls before implementing widely-accepted and adopted industry safety measures.

98. Adopting these ready-to-eat food safety standards well before the outbreak and recall would have prevented the widespread and longstanding contamination of the Blue Bell facilities and products with *Listeria monocytogenes*.

Plaintiff Shockley's Listeriosis Infection

99. In 2013, Plaintiff David Phillip Shockley was thirty-one (31) years old and living in Houston, Texas. He worked as the Associate Executive Director and Nursing Facility Administrator at a 462-apartment continuing care retirement community.

100. Prior to becoming Associate Executive Director, Plaintiff graduated *cum laude* with degrees in Political Science and Information Systems from the University of Maryland, Baltimore County where he went on to obtain a Master's Degree in Public Policy with a focus on aging.

101. In 2013, Plaintiff's employer purchased single serving Blue Bell ice cream and other Blue Bell ice cream products.

102. While at work, Plaintiff regularly consumed single-serving Blue Bell ice cream products and occasionally other Blue Bell ice cream products.

103. Plaintiff also consumed retail Blue Bell products in a variety of sizes and flavors.

104. Some or all of the Blue Bell ice cream products consumed by Plaintiff contained *Listeria monocytogenes*.

105. Upon information and belief, the only food products contaminated with *Listeria monocytogenes* and consumed by Plaintiff prior to his infection were Blue Bell ice cream products.

106. Upon information and belief, some or all of the single-serving Blue Bell ice cream products consumed by Plaintiff at the retirement community were produced at Blue Bell's production facility in Broken Arrow, Oklahoma.

107. Plaintiff suffers from ulcerative colitis and began taking immunosuppressive medications in 2012 and continued to do so throughout 2013. The drugs left him particularly vulnerable to food contaminated with *Listeria monocytogenes*.

108. In late October of 2013, he developed a very severe headache with nausea and light sensitivity. The headache reached such a level of pain and severity that he called 911 for an ambulance.

109. Emergency department personnel diagnosed him with a migraine and discharged him home.

110. Several hours later he lost consciousness.

111. After he missed a work function and failed to respond to emails, calls and text messages, Plaintiff's friends and colleagues went to his home. Thankfully, they discovered Plaintiff alive.

112. Though alive, he was un-responsive, pale, febrile, and in clear respiratory distress. He was rushed to the hospital by ambulance.

113. Emergency personnel recorded that his temperature was 106 to 107 degrees. He was admitted into the intensive care unit in acute respiratory failure, septic shock and suffering from seizure encephalopathy. He spent about five (5) days on artificial respiration and did not fully regain consciousness for approximately six (6) days.

114. To his horror, when he did regain consciousness, he was unable to walk, talk, swallow, or move much of his body.

115. He remained in the intensive care unit (ICU) where he suffered a small sub-acute infarct in his left occipital lobe, which later caused significant vision issues, including, but not limited to, double vision, blurriness and an inability to focus.

116. During his acute illness and ICU treatment, doctors performed a percutaneous endoscopic gastrostomy, a procedure in which a flexible feeding tube is placed through the abdominal wall and into the stomach for nutrition. This feeding tube remained in place until May of 2014.

117. During the course of his treatment, doctors performed a spinal tap and tested his cerebrospinal fluid (CSF).

118. Plaintiff's CSF was positive for *Listeria monocytogenes*. His doctors therefore definitively diagnosed him with *Listeria* meningitis with encephalitis.

119. After approximately eighteen (18) days, he was discharged from the hospital's ICU to an inpatient rehabilitation program.

120. At discharge, Plaintiff remained unable to speak or walk and required around-the-clock assistance.

121. After weeks of grueling inpatient rehabilitation, he was finally allowed to return home. He spent the next several months completing a rigorous outpatient rehabilitation program while receiving assistance with a range of daily tasks.

122. Eventually, Plaintiff moved back to his childhood home in Snow Hill, Maryland where his parents could more easily care for him.

123. From his parents' home in Maryland, Plaintiff received and continues to receive a variety of rehabilitation services and has undergone numerous neurological and other medical

consultations, including evaluation at the Mayo Clinic in Rochester, Minnesota and at the Johns Hopkins Medical Center in Baltimore, Maryland.

124. Because of his severe neurological impairment, long hospitalizations and ongoing treatment, he has been unable to work and now lives with his parents who continue to care for him today.

125. As described in Plaintiff's medical records from a December 14, 2014 visit to the Mayo Clinic, "there is no cure or therapy other than continued physical therapy for his residual neurologic deficits and cerebellar atrophy."

126. Thus, his condition is permanent.

127. The source of the *Listeria monocytogenes* that caused his infection was one or more of the Blue Bell products he consumed in the months leading up to his acute infection.

128. Upon information and belief, in the months prior to his listeriosis infection, Plaintiff was not exposed to any food product contaminated with *Listeria monocytogenes* other than the Blue Bell ice cream products he regularly consumed.

129. As a direct and proximate result of consuming contaminated Blue Bell products, Plaintiff contracted listeriosis and has suffered, and will continue to suffer, the following injuries and damages:

- a. Past medical, hospital, rehabilitation, pharmacy and other similar treatment expenses which already amount to more than four hundred thousand dollars (\$400,000.00);
- b. Future medical, hospital, rehabilitation, pharmacy and other similar treatment expenses for the rest of his life;
- c. Significant and permanent brain damage and other personal injuries;

- d. Physical and mental pain, including diminished enjoyment of life;
- e. Significant past and future disability, including ataxic dysarthria, persistent dizziness, inability to balance and coordinate movements, fine motor skill impairment, dysphagia, slowed cognitive processing and slowed movements;
- f. A loss of earnings of at least one hundred eighty-five thousand dollars (\$185,000.00) and a loss of future earning capacity; and
- g. Other harms, losses and injuries as to be proven at trial.

FIRST CAUSE OF ACTION
STRICT PRODUCT LIABILITY

130. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

131. Blue Bell manufactured, distributed, marketed and sold the ice cream products that caused Plaintiff's listeriosis infection.

132. The Blue Bell ice cream products that Plaintiff consumed were contaminated with *Listeria monocytogenes* when they left Defendants' control and the products reached Plaintiff in substantially the same condition.

133. Ice cream that is contaminated with *Listeria monocytogenes* is extremely and unreasonably dangerous if eaten and is particularly dangerous to the elderly, the immune-compromised, like Plaintiff, and pregnant women.

134. Because *Listeria* is colorless and odorless, consumers, like Plaintiff, have no way of detecting the contamination.

135. The Blue Bell ice cream products consumed by Plaintiff were contaminated with *Listeria monocytogenes* and therefore defective and unreasonably dangerous to ordinary consumers.

136. The Blue Bell ice cream consumed by Plaintiff lacked any warning to consumers. Specifically, Blue Bell failed to warn that its ice cream could be contaminated and may pose a particular risk to the elderly, immune-compromised and pregnant women.

137. Because its single serve products were sold to institutions like hospitals and nursing homes, including the nursing home where Plaintiff worked, the risks posed by those products were particularly foreseeable.

138. Blue Bell is strictly liable to the Plaintiff for the harm caused by the manufacture, distribution, marketing and sale of its dangerous and defective ice cream and for its failure to warn of foreseeable risks to ordinary consumers.

139. As a result of Blue Bell's manufacture, distribution, marketing and sale of defectively manufactured ice cream products and its failure to warn, Plaintiff sustained the injuries and damages set forth in the preceding paragraphs.

SECOND CAUSE OF ACTION
NEGLIGENCE

140. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

141. Defendants manufactured, distributed, marketed and sold ice cream products contaminated with *Listeria monocytogenes*, including the products that sickened Plaintiff.

142. Defendants owed a duty to the consumers of its product, including Plaintiff, to manufacture ice cream that was: safe to eat; not adulterated with deadly pathogens like *Listeria*

monocytogenes; produced pursuant to industry safety standards; and produced in compliance with applicable food safety regulations. Defendants breached this duty.

143. Defendants breached the duties owed to the consumers of its ice cream products by committing the following acts and omissions:

- a. Failing to adequately maintain and monitor the safety of its products, premises, equipment and employees;
- b. Failing to properly operate its facilities and equipment in a safe, clean and sanitary manner;
- c. Failing to adopt adequate food safety policies and procedures;
- d. Failing to apply its food safety policies and procedures to ensure the safety and sanitary conditions of its food products, premises and employees;
- e. Failing to apply food safety policies and procedures that met industry standards for the safe and sanitary production of food products and the safety and sanitary conditions of its premises and employees;
- f. Failing to prevent the transmission of *Listeria monocytogenes* to consumers of its ice cream products;
- g. Failing to properly train its employees and agents how to prevent the transmission of *Listeria monocytogenes* on its premises, from its facility or equipment or in its food products;
- h. Failing to properly supervise its employees and agents to prevent the transmission of *Listeria monocytogenes* on its premises, from its facility or equipment or in its food products;

i. Failing to adequately test its ice cream products and processing environment for microbial pathogens, like *Listeria monocytogenes*, and failing to respond to testing that indicated the presence of *Listeria* and other microorganisms; and

j. Other acts and omissions as discovered through discovery.

144. As a direct and proximate result of Defendants' negligence, Plaintiff consumed Blue Bell ice cream contaminated with *Listeria monocytogenes* and subsequently contracted listeriosis.

145. As a direct result of Defendants negligence, Plaintiff sustained the injuries and damages set forth in the preceding paragraphs.

THIRD CAUSE OF ACTION
NEGLIGENCE PER SE
(Texas Health and Safety Code § 431.001 et seq.)

146. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

147. Defendants, as providers of food products in the State of Texas, owe a duty to comply with Texas Health and Safety Code § 431.021, which states in part:

The following acts and the causing of the following acts within this state are unlawful and prohibited:

- a. the introduction or delivery for introduction into commerce of any food ... that is adulterated or misbranded;
- b. the adulteration or misbranding of any food ... in commerce;
- c. the receipt in commerce of any food ... that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise...

148. Pursuant to the Texas Health and Safety Code § 431.081, a food is “adulterated” if it “bears or contains any poisonous or deleterious substance which may render it injurious to health.” Thus, any ready-to-eat product contaminated with *Listeria monocytogenes* is adulterated and in violation of Texas law.

149. The Texas law is designed to protect food consumers, like Plaintiff, from illness caused by contamination. Plaintiff is therefore in the class of people to be protected by the law.

150. By manufacturing, distributing, and selling ice cream contaminated with *Listeria monocytogenes*, Defendants violated the Texas Food, Drug and Cosmetic Act and were therefore negligent *per se*.

151. As a direct and proximate result of Defendants’ negligence, Plaintiff consumed Blue Bell ice cream contaminated with *Listeria monocytogenes* and subsequently contracted listeriosis.

152. As a direct result of Defendants’ negligence, Plaintiff sustained the injuries and damages set forth in the preceding paragraphs.

FOURTH CAUSE OF ACTION
NEGLIGENCE PER SE
(21 U.S.C. § 331 et seq.)

153. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

154. Defendants, as providers of food products in the United States of America, owe a duty to comply with 21 U.S.C. § 331, which states in part:

The following acts and the causing thereof are prohibited:

- a. The introduction or delivery for introduction into interstate commerce of any food ... that is adulterated or misbranded;

b. The receipt in interstate commerce of any food that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise.

155. Pursuant to 21 U.S.C. § 342, a food is “adulterated” if it “bears or contains any poisonous or deleterious substance which may render it injurious to health.” Thus, any ready-to-eat product contaminated with *Listeria monocytogenes* is adulterated and in violation of federal law.

156. The federal law is designed to protect food consumers, like Plaintiff, from illness caused by contamination. Plaintiff is therefore in the class of people to be protected by the law.

157. By manufacturing, distributing, and selling ice cream contaminated with *Listeria monocytogenes*, Defendants violated 21 U.S.C. § 331 and were therefore negligent *per se*.

158. As a direct and proximate result of Defendants’ negligence, Plaintiff consumed Blue Bell ice cream contaminated with *Listeria monocytogenes* and subsequently contracted listeriosis.

159. As a direct result of Defendants negligence, Plaintiff sustained the injuries and damages set forth in the preceding paragraphs.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

160. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

161. By offering its ice cream products for sale to the general public, Blue Bell impliedly warranted that its products were safe to eat, not adulterated with a deadly pathogen and prepared safely under sanitary conditions.

162. Defendants breached the implied warranties with regard to the ice cream products it manufactured and sold to the public, including the products consumed by Plaintiff, because the

contaminated products: would not pass without objection in the trade; were not of fair average quality; and were not fit for the ordinary purpose for which ice cream products are used, human consumption.

163. As a direct result of Defendants' breach of implied warranties, Plaintiff sustained the injuries and damages as set forth above.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

164. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

165. Defendants marketed their ice cream products on websites, in print, and on their product's packaging as wholesome and safe.

166. For example, in 2013, Blue Bell represented on its website that it used "the finest milk, cream, sugar and other ingredients money can buy," and that it used "special skills and knowledge" in the production of its ice cream products.

167. On its packaging, Blue Bell proclaimed "we're picky about what goes into" its ice cream and that the company "choose[s] only the freshest and finest ingredients money can buy."

168. Neither its website, packaging or other marketing materials ever stated that its products were produced in a processing environment infested with *Listeria monocytogenes* and other microorganisms or that it knowingly and repeatedly shipped products produced at the same time it detected the presence of *Listeria* and elevated coliform counts.

169. The information on its websites, packaging and other marketing materials was therefore false.

170. Defendants failed to exercise reasonable care and competence in communicating about the quality of its product because, among other reasons, its production systems and safety programs were well below industry standards.

171. Plaintiff justifiably relied on Blue Bell's public representations about quality and safety of its products in that he consumed them, in part, because he trusted that Blue Bell's products were in fact made of only of the finest ingredients and that Blue Bell cared what went into its products.

172. As a direct result of Defendants' negligent misrepresentations, Plaintiff sustained the injuries and damages set forth in the preceding paragraphs.

SEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES

173. Plaintiff incorporates all of the preceding paragraphs by reference as if each were set forth here.

174. Prior to Plaintiff's illness, Defendants knew that *Listeria monocytogenes* was an extremely dangerous foodborne pathogen.

175. Prior to Plaintiff's illness, Defendants knew that its products, specifically its single-serve ice cream products, were being consumed by children, the elderly, those hospitalized and in nursing homes, and those with suppressed immune systems.

176. Prior to Plaintiff's illness, Defendants knew that environmental and product testing in its production facilities yielded results indicating *Listeria* contamination of the processing environment and elevated coliform levels in its finished ready-to-eat ice cream products.

177. Prior to Plaintiff's illness, Defendants knew its routine cleaning and sanitation procedures and practices were not eliminating the risk of contamination by microorganisms, including *Listeria monocytogenes*.

178. Despite this actual knowledge, Defendants intentionally shipped, without warning or subsequent recall, a variety of ice cream products produced at the same times and places as the samples that tested positive.

179. Further, knowing that it was routinely failing to clean its processing environment and was producing finished products with abnormally high coliform counts, Defendants took no action to fix, modify or otherwise change its safety and sanitation operations.

180. In doing so, Defendants intentionally created an extreme risk to the consumers of its products.

181. Whether for increased profit or out of profound and gross negligence, Defendants thereby acted with conscious indifference to the rights, safety and welfare of the general public, including Plaintiff.

182. As a direct result of Defendants' gross negligence and intentional disregard for the safety of the public, Plaintiff sustained the injuries and damages set forth in the preceding paragraphs.

183. As a result of the foregoing acts and omissions, Plaintiff is entitled to assert a claim for punitive damages against Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of his claims and Causes of Action as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life and other non-economic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, lost earning capacity and other economic damages in an amount to be determined at trial of this action;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff, in an amount sufficient to punish Defendants and deter future similar conduct;

4. Prejudgment interest;

5. Postjudgment interest;

6. Awarding Plaintiff the costs of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Date: May 19, 2015

Respectfully submitted,

/s/ John Volney

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